

REMARKS

Claims 1-29 are pending in the present application.

The Applicant would like to thank Examiner Woitach for the helpful and courteous discussion with his undersigned Representative on March 20, 2003.

The rejection of Claims 6-17 under 35 U.S.C. §102(e) over Yamashita (EP 1 180 684 A1) is traversed.

As is evidenced by the front page of Yamashita and the notice of priority filed on June 29, 2001 (a copy of which is enclosed herewith with a copy of date-stamped filing receipt for the Examiner's convenience), each of these applications claims priority to JP 2000-247729. Further, Yamashita is not based on a PCT application, but rather was filed directly in the European Patent Office with a claim to priority under the Paris Convention. Therefore, Yamashita is the EPC counterpart to the present application. Moreover, the Applicant notes that Yamashita was not published until February 20, 2002, while the present application was filed on June 29, 2001. Therefore, for each of the reasons stated hereinabove, Yamashita should not be available as prior art under 35 U.S.C. §102.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 10 and 11 under 35 U.S.C. §102(e) over Kawahara et al is traversed.

The Applicant makes no statement with respect to the propriety of the rejection over Kawahara et al. However, enclosed herewith is a Declaration under 37 C.F.R. §1.131 executed by Tetsuya Kawahara, Hisashi Okada, and Ichiro Yamashita who depose and state that they are named as authors of Kawahara et al (2000) Cloning and Expression of Genomic and Complementary DNAs Encoding an Estrogen Receptor in the Medaka Fish, *Oryzias*

latipes. Zoological Science 17: 643-649. Tetsuya Kawahara, Hisashi Okada, and Ichiro Yamashita further depose and stated that Ichiro Yamashita is the named inventor of U.S. Application 09/893,666, filed on June 29, 2001 and that the disclosure of Kawahara et al relied upon by the Examiner to reject the claimed invention is the disclosure of Applicant's own work and is not the work of another. Moreover, this Declaration states that Kawahara and Okada were only assistants in carrying out the experiments.

Therefore, it is believed that this reference should not be available as prior art. In view of the enclosed Declaration under 37 C.F.R. §1.131, withdrawal of this ground of rejection is requested.

The rejection of Claims 6-17 under 35 U.S.C. §112, first paragraph, is obviated in part and traversed in part.

In making this ground of rejection, the Examiner has determined that the specification lacks enablement "for medaka fish which do not express the estrogen receptor, for other promoters besides the beta-actin promoter, or for the use of transgenic medaka fish which do not develop thrombi" (paper number 28, page 5, lines 16-19). Pursuant to the Examiner's helpful suggestion to Applicant's undersigned Representative, the claims have been amended to specifically indicate that the polynucleotide having a nucleotide sequence of SEQ ID No: 1 (see Claim 6), a nucleotide sequence corresponding to nucleotides 211 to 1935 of SEQ ID No: 1 (see Claims 7 and 18), or a polynucleotide encoding an amino acid sequence of SEQ ID No: 2 (see Claim 24) is expressed. In addition, Applicants have also stipulated that expression thereof produces one or more thrombi.

With respect to the identity of the promoter, Applicant submits that the artisan would readily appreciate the operable scope of promoter sequences that are compatible with the expression source and expression vector selected. Accordingly, no particular limitation is

imposed upon the identity of the promoter sequence so long as it meets the limitation of the claims. In other words, the promoter in one "which is capable of expressing sufficient amounts of a protein encoded by said polynucleotide to produce one or more thrombi."

However, in order to provide the artisan with a measure of guidance to fully appreciate the scope of the invention, Applicant points to page 5, line 12 to page 7, line 4, which disclose cloning and preparation of a recombinant vector. On page 7, line 5 to page 9, line 16, Applicant provides a description of the preparation of transgenic medaka fish. On page 9, line 17 to page 10, line 18, Applicant describes the preparation of medaka fish having one or more thrombi. And, on page 10, line 19 to page 12, line 3, Applicant provides a method of testing an estrogen-like acting substance by growing the transgenic fish of the present invention. Moreover, on pages 12-25, the Applicant provides a full example of an actual experiment performed in accordance with the description highlighted above.

MPEP §2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Therefore, for the reasons detailed above, the Applicant has met his burden of clearly defining the scope of the present invention. As such, withdrawal of this ground of rejection is requested.

The rejections of Claims 8-17; of Claims 10 and 11; and of Claims 12 and 13, each under 35 U.S.C. §112, second paragraph, is obviated by amendment.

The Applicant wishes to thank Examiner Woitach for the helpful suggestions to address these grounds of rejection. Applicant requests withdrawal of these grounds of

rejection.

The objection to Claims 6 and 7 (and claims dependent therefrom) as encompassing the products of non-elected Claims 1 and 2 is obviated by the present amendment. As recommended by the Examiner, Applicant has amended Claims 6 and 7 to recite the incorporated elements of non-elected Claims 1 and 2. Withdrawal of this objection is requested.

On page 1 (PTO-326) of paper number 28 (Office Action mailed January 17, 2003), the Office objects to the drawings filed on June 29, 2001. To support this objection the Office attached to this communication Form PTO 948. However, Applicant believes that this objection was an error on the behalf of the Office. As evidenced by the enclosed date-stamped filing receipt of June 29, 2001, no drawings were filed in this application. In addition, Applicant notes that Form PTO-948 bears a serial number of 09/155, 452. Therefore, Applicant believes that no further action on their behalf is required and withdrawal of this objection is requested. If Applicant's understanding is incorrect, Applicant respectfully requests that the Examiner contact his undersigned Representative at his earliest convenience to resolve this issue.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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IN THE CLAIMS

Please amend the claims as follows:

6. (Amended) [Transgenic] A transgenic medaka fish [into which the polynucleotide according to claim 1 is introduced] comprising a polynucleotide having a nucleotide sequence of SEQ ID No: 1, wherein said polynucleotide contains a promoter sequence, which is capable of expressing sufficient amounts of a protein encoded by said polynucleotide to produce one or more thrombi.

7. (Amended) [Transgenic] A transgenic medaka fish [into which the polynucleotide according to claim 2 is introduced] comprising a polynucleotide having a nucleotide sequence corresponding to nucleotides 211 to 1935 of SEQ ID No: 1, wherein said polynucleotide is operably linked to a promoter sequence, which is capable of expressing sufficient amounts of a protein encoded by said polynucleotide to produce one or more thrombi.

8. (Amended) A method of producing transgenic medaka fish having one or more thrombi, comprising [the step of] raising the transgenic medaka fish [according to] of claim 6 in the presence of estrogen.

9. (Amended) A method of producing transgenic medaka fish having one or more thrombi, comprising [the step of] raising the transgenic medaka fish [according to] of claim 7 in the presence of estrogen.

10. (Amended) [Medaka] A transgenic medaka fish having one or more thrombi, which is obtained by raising the transgenic medaka fish [according to] of claim 6 in the

presence of estrogen.

11. (Amended) [Medaka] A transgenic medaka fish having one or more thrombi, which is obtained by raising the transgenic medaka fish [according to] of claim 7 in the presence of estrogen.

12. (Amended) A method of testing an estrogen-like [action] activity in test water, comprising [the steps of]:

raising the transgenic medaka fish [according to] of claim 6 in test water; and

observing whether or not one or more thrombi are formed in the medaka fish after [the] said raising [step].

13. (Amended) A method of testing an estrogen-like [action] activity in test water, comprising [the steps of]:

raising the transgenic medaka fish [according to] of claim 7 in test water; and

observing whether or not one or more thrombi are formed in the medaka fish after [the] said raising [step].

14. (Amended) The method according to claim 12, wherein the test water is water taken from the environment.

15. (Amended) The method according to claim 13, wherein the test water is water taken from the environment.